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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,862	07/12/99	THORPE	P 4001.002282

HM22/0129

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EXAMINER	
SHARAREH, S	
ART UNIT	**PAPER NUMBER**
1619	13

DATE MAILED: 01/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/351,862	Thorpe et al
Examiner	**Group Art Unit**
Shahnam Sharar h	1619

☒ Responsive to communication(s) filed on *Nov 14, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-38* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Claims 1-38 are pending. Applicant's provisional election of a kit comprising an antibody that binds to phosphatidylserine and an anti-cancer agent is acknowledged. However, the provisional election made on Paper No. 12 filed on November 14, 2000 is not fully responsive to the communication filed on September 21, 2000, because Applicants have not recited the exact Group or specified the claims directed to their provisional election. Therefore, in view of Applicant's arguments, the Examiner has regrouped the previous restriction requirement to expedite the prosecution of instant application.

Response to Arguments

Applicant's traversal is on the basis that claims 1, and 38 are linking claims which properly joins the various embodiments of the overall invention and thus most other claims are subgeneric to a variety of species. Applicant further asserts that the instant claims rather than being distinct are at best, separate species within a proper generic invention, and that Patent Office has not provided reasoning adequate to show that the invention of Group I through IV are properly restrict able or distinct.

In view of Applicant's traversal, Examiner has reconsidered the previous restriction requirement and has modified the previous requirement as is presented below. However, Examiner would like to address the followings issues in response to Applicant's arguments.

The question in the instant restriction requirement is whether the instant kits comprising said first antibody or antigen-binding fragment thereof, and detectably labeled antibody or antigen-binding thereof and the second anti-cancer agent are patentably distinct kits when

comprise additional targeting, therapeutic or diagnostic compositions. It is clearly inferred from the claims, for example in claim 12, that utilizing a second antibody or antigen binding fragment thereof binding to a different amino phospholipid such as phophatidylserine constitutes an additional component. Therefore, the essential elements that are used to prepare the instant kits are dissimilar, rendering the kits as a whole patentably distinct from each other. Furthermore, the claims directed to kits that are used for imaging purposes contain compositions comprising diagnostically effective amount of a detectably-labeled antibody which are materially different ingredients when compared to kits that are used for treatment purposes. Also, Applicant has not provided any evidence or identify such evidence now of record showing that the claimed species are obvious variants or clearly admit on the record that this is the case.

Accordingly, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 14-30, 34-38 in part, drawn to kits comprising at least one antibody or antigen-binding fragment thereof, a detectably-labeled antibody and a second anti-cancer agent optionally comprise a targeting agent and a cytotoxic agent, classified in class 530, subclass 388.8+.

II. Claims 1, 12-13 in part, drawn to kits comprising two antibody or antigen-binding fragments that bind to an aminophospholipids, classified in class 514, subclass 2+.

III. Claims 31-33, drawn to an imaging kit comprising two separate pharmaceutical compositions, classified in class 424, subclass 1.11+.

1. Inventions I and II or III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because kits for treatment of tumors does not require a diagnostically effective construct or a second antibody or anti-cancer agent. In the case of Group II, the subcombination contains materially and structurally different components. Thus, their end products are materially distinct from Group I kits, and can seperately be utilized for treatment of various tumors by themselves. In the case of Group III, the subcombination has separate utility such imaging the localized region of a vascularized tumor. Further, kits that are utilized for imaging with or without a second anti-cancer agent need materially different products, process steps and possess distinct endpoints.

2. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable see MPEP § 806.05(d). In the instant case, invention III has separate utility such as imaging a localized region of a vascularized tumor. Clearly one skilled in the art could readily practice the invention II without practicing invention III, since kits that are used for diagnostic methods are clinically independent from kits that are used for therapeutic purposes. Further each invention utilize different methods of practice.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required

for each Group is not required for the others, restriction for examination purposes as indicated is proper.

This application contains claims that are drawn in Markush format and are directed to the following patentably distinct species of the claimed invention:

I) Various first antibody or antigen binding fragments thereof directed to aminophospholipids wherein said antibody or antigen binding fragment is directed to a specific aminophospholipid. Further the instant claims are also directed to different types of antibodys wherein they are monoclonal, recombinant or humanized, etc.. (claims 1-9).

II) Various second anti cancer agent wherein said agent is a chemotherapeutic, a radiotherapeutic, an anti-angiogenic, an aptoptosis-inducing agent, or an antibody-therapeutic agent construct (claims 1, 20-22).

III) Various types of second anti-cancer agents in the form of antibody-therapeutic agent construct (claims 1, 23-29).

III) Various targeting antibodies directed to a specific cell surface site (claims 1, 23-29).

IV) Kits comprising a targeting agent-detectable agent, wherein detectable agent comprise X-ray compounds or radioactive ions or nuclear magnetic agents (claim 1, 16-18, 30-31).

V) Kits comprising at least a second anti-cancer agent (claims 1, 24-31, 37-38).

The instant species are considered to be independent since they are unrelated in operation, one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered to be patentably distinct from the others on the basis of its properties. Thus, the stated species are capable of

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supporting separate patents under 35 U.S.C. 121. In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration.

Accordingly, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from the elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, if elected Group I Applicant is required to elect a single disclosed species for the specific amino phospholipid, the specific type of antibody (if it is a monoclonal, recombinant or humanized antibody) or the specific antigen-binding fragment thereof, the specific type of the diagnostic agent (an X-ray, a radio nuclide or a detectable nuclear magnetic spin resonance isotope), and a specific second anti-cancer agent. If Applicant elects the antibody-therapeutic agent construct as the second anti-cancer agent, then applicant is required to further elect the specific antibody, its respective surface-expressed component and the cytotoxic agent that is used to prepare such construct (claims 22-29). Applicant is advised to select such species taught in the specification. It is noted that the claims encompass such final products as those set forth in Examples III-X and listed on pages 104-168 of the specification.

Currently, claims 1, 31, 34, 37-38 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

ss 1/18/2001

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